## DETAILED ACTION

1. This Office Action is a response to the amendment(s) and remarks filed on February 17, 2009. Claims 1, 3-11, 19 and 21-23 have been amended; claims 13-18 and 24-26 have been cancelled; no claims have been added. The Restriction requirement has been made FINAL.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2009 has been entered.

3. Claims 1-12 and 19-23 are now pending.

## EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Thomas M. Cunningham (Reg. No. 45,394) on February 23, 2009.

5. Claim 3, line 6: after the word "and" delete the numbers "20 to 45%".

Claim 8, line 1: after the word “polymer” delete the remaining part of the claim and insert – according to claim 1, further comprising a pharmaceutically effective natural or synthetic biomolecule or an active pharmaceutical ingredient. --.

Claim 21, line 1: after the word “polymer” delete the remaining part of the claim and insert – according to claim 1, wherein said pH-sensitive polymer is produced by polymerizing methacrylic acid and ethylacrylate in the presence of a molecular weight regulator which incorporates on a terminal of said polymer. --.

***Allowable Subject Matter***

6. Claims 1-12 and 19-23 are allowed.

7. The following is examiner’s statement of reasons for allowance:

8. The present claims are allowable over the closest references: Haddleton et al. (U. S. Patent 5,804,632) and Rehmer et. al. (U. S. Patent 6,225,401).

Haddleton discloses a production of an aqueous polymer emulsion comprises a low molecular weight polymer containing acid-functional groups made by using a free-radical polymerization process which employs a free-radical initiator and, for the purpose of controlling molecular weight, a transition metal chelate complex, wherein said low molecular weight polymer has a number average molecular weight within the range of from 500 to 50,000 (abstract).

Typically the acid-bearing comonomers are olefinically unsaturated carboxyl-functional monomers such as mono carboxyl-functional acrylic monomers and olefinically unsaturated dicarboxyl bearing monomers; examples include acrylic acid,

methacrylic acid, itaconic acid, maleic acid and fumaric acid (col. 5, lines 41-46). Non-acid functional monomers, which may be copolymerized with the acid monomers, include alkylmethacrylates and styrenes, and alkylacrylates can also be used, particularly if included as comonomers at low levels. Typically, the acid functional low molecular weight polymer is derived from a monomer system which contains 1-60 weight % of acid comonomer(s), and correspondingly 99-40 weight % of non acid functional comonomer(s) (col. 6, lines 17-23). The low molecular weight polymer should have a number average molecular weight within the range of from 500-50,000, preferably 700-20,000 and particularly 1,000-10,000 (col. 7, lines 8-10).

Haddleton discloses an aqueous emulsion polymerization process to form an aqueous emulsion of a hydrophobic polymer from at least one olefinically unsaturated monomer, wherein the low molecular weight polymer is introduced to the aqueous medium of said emulsion polymerization process before the start of and/or during said emulsion polymerization process and becomes dissolved or dispersed in said aqueous medium (abstract). The polymerization process can be carried out in the presence of a polymerization medium (acting as a carrier medium for the components and as a heat transfer medium) or in the absence of such a medium (i.e. in bulk) (col. 4, lines 21-24).

Haddleton discloses that methacrylates include normal or branched alkyl esters of C1 to C12, especially C1 to C10, alcohols and methacrylic acid, (i.e. C1 to C12, especially C1-10, alkyl methacrylates) such as methyl methacrylate, ethyl methacrylate, n-butyl methacrylate and lauryl methacrylate. Acrylates include normal and branched alkyl esters of C1 to C12, especially C1 to C10, alcohols and acrylic acid, (i.e. C1-C12,

especially C1-10, alkyl acrylates) such as methyl acrylate, ethyl acrylate, n-butyl acrylate and 2-ethylhexyl acrylate (col. 5, lines 53-67). There is a mixture of MMA (mehyl methacrylate), BMA (butyl methacrylate) and MAA (methacrylic acid) used for the preparation of the copolymer in LMP 10 (low molecular weight polymer) (col. 16 line 65 through col. 17, line 13).

One or both of the low molecular weight polymer and the hydrophobic polymer possess functional groups for imparting latent crosslinkability to the composition (i.e. so that crosslinking takes place e.g. after the formation of a coating therefrom). Alternatively, one or both polymers could carry functional groups such as hydroxyl groups and the composition subsequently formulated with a crosslinking agent such as a polyisocyanate, melamine, or glycouril; or the functional groups on one or both polymers could include keto or aldehyde carbonyl groups and the subsequently formulated crosslinker could be a polyamine or polyhydrazide such as adipic acid dihydrazide (col. 11, lines 10-27).

Rehmer discloses a process for producing readily filterable and deodorizable, highly concentrated, aqueous dispersions of pressure-sensitive adhesive, having readily reproducible properties, on the basis of copolymers of esters of acrylic and/or methacrylic acid, by emulsion polymerization in the presence of customary emulsifiers and free-radical polymerization initiators in accordance with the monomer emulsion feed polymerization technique, in which the monomer emulsion is run in a feed stream into the polymerization reactor, which comprises conducting the emulsion polymerization of a monomer mixture comprising (A) at least 50% by weight of the overall monomer

amount of at least one ester of acrylic and/or methacrylic acid with alcohols of 1 to 18 C atoms and (B) other olefinically unsaturated monomers (col. 2, lines 22-37).

Rehmer discloses that in the polymerization reaction it is also possible to add regulators, especially in amounts of up to 0.5% by weight of the amount of monomers, which reduce the degree of polymerization of the resulting emulsion polymers. Examples of such regulators are mercaptans, such as tert-dodecyl mercaptan, ethylhexyl thioglycolate, or 3-mercaptopropyltrimethoxysilane, or unsaturated compounds with allylic hydrogens, such as butenol (col.3, lines 31-38).

Applicants disclose that the pH-sensitivity of the claimed polymers is not inherent to the genus of acrylamide or acrylic acid based copolymers of the prior art as shown by the comparative examples of copolymers Tables 1-5 in the specification. Table 1 shows the composition of polymers B and C (according to the invention) and A, D, E, L-100, L-100-55 and S-100 which fall outside of the claims; for example, table 4 shows that polymers B and C have the pH-sensitivity required by the claims, but that the other comparative polymers do not.

However, Haddleton et al. and Rehmer et al. do not disclose or fairly suggest the claimed pH-sensitive polymer, which comprises ethylacrylate in an amount between 35-60 wt.% (or 35-50 wt.%) and methacrylic acid in an amount ranging from 25-65 wt.%, and has the following unique properties: at a concentration of 150 µg/ml in a cytotoxicity test with human red blood, about at least 60% haemolysis at pH 5.5, and less than 5% haemolysis at pH 7.4, as per newly amended claims 1-12 and 19-23.

9. As of the date of this Notice of Allowability, the Examiner has not located or identified any reference that can be used singularly or in combination with another reference including Haddleton et al. and Rehmer et al. to render the present invention anticipated or obvious to one of ordinary skill in the art.

10. In the light of the above discussion, it is evident as to why the present claims are patentable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delay, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reason for Allowance".

## ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL M. BERNSHTEYN whose telephone number is (571)272-2411. The examiner can normally be reached on M-Th 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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